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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/616,371	03/15/96	STAMLER	DUK96-03PA

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EXAMINER
CELSA, B

ART UNIT	PAPER NUMBER
1627	32

DATE MAILED: 01/12/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
08/616,371

Applicant(s)  
Stamler et al.

Examiner  
Bennett Celsa

Group Art Unit  
1627



☒ Responsive to communication(s) filed on Oct 23, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 4, 9, 12, 16-30, 33, and 34 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☒ Claim(s) 4, 16-30, 33, and 34 is/are allowed.

☒ Claim(s) 9 and 12 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## **DETAILED ACTION**

### ***Response to Amendment***

Applicant's amendment dated 10/23/00 in paper no. 31 is hereby acknowledged.

### ***Status of the Claims***

Claims 4, 9, 12 and 16-30 and 33-34 are currently pending and under consideration..

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Allowable Subject Matter***

2. Claims 4 and 16-30 and 33-34 are allowable over the prior art of record.

### ***Withdrawn Objection (s) and/or Rejection (s)***

Applicant's cancellation of claims 31 and 32 has overcome the new matter rejection of these claims.

Applicant's cancellation of claims 10 and 13 has overcome the rejection of these claims under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling.

Applicant's cancellation of claim 15 has overcome the rejection of this claims under 35 U.S.C. 103(a) as obvious over Stamler et al, WO 93/09806 (5/93).

Applicant's cancellation of claim 5 has overcome the rejection of this claims as being unpatentable over Stamler et al. in view of Feola et al., U. S. Pat. No. 5,439,882 (8/95: filed 5/93 or earlier) and Hunter, U.S. Pat. No. 5,152,979 (10/92).

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Applicant's cancellation of claims 31 and 32 has overcome the rejection of these claims under 35 U.S.C. 102(b) as being anticipated by or alternatively under 35 USC 103 as being obvious over Chem. Res Tox. 1990 Vol. 3, pages 289-291.

***Outstanding Objection (s) and/or Rejection (s)***

3. Claims 4-5, 9-10,12-13 and 15-34 of this application conflict with claims which are present in Application No.08/667,003 and 08/796,164. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

***Discussion***

The above double patenting issue was not specifically addressed by applicant.

Accordingly, the above double patenting rejection is hereby maintained.

4. It is noted that allowable subject matter has been indicated . Accordingly, at the time of allowance, related applications will be further evaluated for overlapping subject matter which may (or may not) result in the removal or addition of double patenting rejection(s). Applicant's assistance in this regard would be appreciated

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*New Objection (s) and/or Rejection (s)*

5. Claims 9 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by or alternatively under 35 USC 103 as being obvious over Wade and Castro, Chem. Res Tox. 1990 Vol. 3, pages 289-291 alone and further in view of the specification and claim teaching of the method of making S-nitrosylated hemoglobin in order to demonstrate inherency. See *Ex parte Novitski*, 26 USPQ2d 1389 (B.P.A.I, 1993) (use of specification example to demonstrate inherency); MPEP 2131.01(d) which permits the citation of references or other extrinsic evidence in an anticipation rejection under 35 U.S.C. 102 in order to show that a characteristic not disclosed in the reference is inherent.

The Wade and Castro reference discloses a method of transferring the nitrosyl group to sulfur (as well as oxygen, nitrogen and sulfur) of heme proteins, including hemoglobin to thus form SNO-hemoglobin by reacting hemoglobin in pH 7.4, 0.01 buffer (see table 1) under anaerobic conditions in excess nitric oxide (e.g. @  $2 \times 10^{-3} \text{M}$ ) (e.g. see page 289 under “Results and Discussion”).

The reference NO and hemoglobin concentrations are within the scope of the presently disclosed and claimed invention for making S-nitrosylated hemoglobin. It is further noted that a “composition” comprising an S-nitrosylated hemoglobin in which additionally other moieties (e.g. carbon, oxygen and nitrogen) may be present are within the scope of the present composition claims.

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The isolation of the nitrosated hemoglobin species and/or the spectrophotometric determination (e.g. page 290) presumably in air would be expected to form the oxyhemoglobin species. Alternatively, it would have been obvious to one of ordinary skill in the art to generate the oxygenated hemoglobin species by air oxidation especially since the reference specifically points to a nitrosation process which occurs under aerobic conditions. E.g see page 290, left column and footnote 4.

Accordingly, the degree of heme oxidation (e.g. “nondetectable”) of the reference nitrosylated hemoglobin would be met inherently by the reference which utilizes a method within the scope of the presently disclosed and claimed invention. The Examiner lacks the facilities to do testing.

### *Discussion*

Applicant’s arguments directed to the above 102/103 rejection were considered but deemed nonpersuasive for the following reasons.

In essence applicant argues that the Wade and Castro reference fails to teach that the reference reaction conditions produce S-nitrosylated hemoglobin without detectable oxidation of the heme Fe.

As recited in the above rejection, the method steps and reagents as presently claimed are specifically taught by the reference. The reference also discloses and suggests S-nitrosylation of hemoglobin. Accordingly, S-nitrosylation “without detectable oxidation of heme Fe” must result (inherently or otherwise) since the reference is practicing the SAME METHOD STEPS as

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presently claimed. Applicant should consider amending the claims to recite claim parameters which distinguish over the reference method.

With regard to the composition claims it is noted that "comprising" is open ended. Since the reference method meets the presently claimed method limitations a composition within the scope of the presently claimed invention must result.

Applicant may consider amending to recite "consisting essentially of" or "consisting of" which would be more consistent with applicant's arguments and Declaration evidence (e.g. by Dr. Stamler and others) of record.

**General information regarding further correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Celsa whose telephone number is (703) 305-7556.



If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat (art unit 1627), can be reached at (703)308-0570.

Any inquiry of a general nature, or relating to the status of this application, should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Bennett Celsa (art unit 1627)

January 11, 2001

**BENNETT CELSA  
PRIMARY EXAMINER**

  
  
12/11/01